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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,099	11/29/2001	Mary Mowrey-McKee	LP/V-31594/A	3645

31781 7590 07/01/2004  
CIBA VISION CORPORATION  
PATENT DEPARTMENT  
11460 JOHNS CREEK PARKWAY  
DULUTH, GA 30097-1556

EXAMINER
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YU, GINA C

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

09/997,099

**Applicant(s)**

MOWREY-MCKEE ET AL.

**Examiner**

Gina C. Yu

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 29, 2004 has been entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 8, 10-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Tsuzuki et al. (US 6417144 B2) ("Tsuzuki").

Tsuzuki discloses a contact lens solution comprising 0.05 – 0.1 w/v % by weight of CAE (N-coconut oil fatty acid acyl L-arginine ethyl-DL-pyrrolidone carboxylate, an amino acid type cationic surfactant), Poloxamer 407 (surfactant), 0.1 w/v % of Bis-Tris EDTA (a chelating agent), NaCl (a tonicity agent), and hydroxypropylmethyl cellulose (a thickener). See Tables 1 and 2; instant claims 1, 2, 5, 10-17. The reference teaches

that the amino acid type cationic surfactant has disinfection power in addition to the cleaning power, which meets the microbicide limitation of instant claim 1. See Tsuzuki, col. 7, lines 9 – 20. The reference also teaches that the pH of the solutions are 7.3. See col. 7, lines 36 – 42; instant claims.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 6, 7, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuzuki et al. (US 6417144) ("Tsuzuki") as applied to claims 1-5, 8, 10-18 above under § 102 (e).

While Tsuzuki fails to teach formulations comprising polyhexamethylene biguanide, the reference suggests using the polymer as a disinfectant. See col. 6, lines 48 – col. 7, line 6.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the formulations in Tsuzuki by substituting the cationic polymer therein with polyhexamethylene biguanide as suggested by the reference because of an expectation of successfully producing a contact lens solution with cleaning and disinfecting properties.

### ***Response to Arguments***

Applicant's arguments filed March 29, 2004 have been fully considered but they are not persuasive.

Applicants assert that the present invention claims priority over the cited reference. In fact, Tsuzuki et al. (US 6417144 B2) has the effective filing date of June 14, 2000, which is prior to the November 29, 2000 date of the present application.

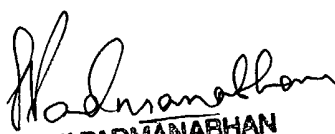
**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-0635. The examiner can normally be reached on Monday through Friday, from 8:30 AM until 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu  
Patent Examiner

  
SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER